

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Cynthia T. Clague et al. Examiner: Pavitra Kotini  
Serial No.: 10/694,037 Group Art Unit: 3731  
Filed: October 27, 2003 Docket No.: M190.242.101/P11210.00  
Title: METHOD AND APPARATUS FOR MAKING PRECISE INCISIONS IN  
BODY VESSELS

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This pre-appeal brief is being submitted along with a Notice of Appeal in response to the Office Action mailed on April 24, 2008. Claims 7-14, 24-31, and 35-46 have been withdrawn from consideration. The pending claims 1-6, 15-23, and 32-34 were rejected. Claims 1-6, 15-23, and 32-34 remain pending in the application and are presented for reconsideration and allowance.

**Claim Rejections under 35 U.S.C. § 103**

Independent claim 1 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Irisawa JP Patent No. 2003-210473. Claims 2-6 and 15-17 depend from independent claim 1, and claims 21-23 and 32-34 depend from independent claims 1 and 18 respectively.

Applicants agree with the Office Action that Shapiro does not disclose that “the first cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending first cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side” as set forth in the Office Action on page 4 and as required in independent claims 1 and 18. Applicants also respectfully traverse that Irisawa teaches or makes obvious these features in the claim.

For example, Irisawa does not teach or make obvious the features of “the first cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending first cutting blade . . . wherein the major portion [of the blunt distal leading blade

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side] extends generally perpendicular to the proximal trailing side” as required in claims 1 and 18. The corresponding feature with the “cutting blade” of the claims in Irisawa is the cutter 32. As set forth in paragraph [0036] of Irisawa, the “cutter 32 is substantially triangular in side shape.” Further, in paragraph [0037], Irisawa states, “The angle  $\theta$  (in degrees) is formed by the needle 31 and the blade 321 on the cutter 32 . . . [is] preferably about 120 to 180°.” Figures 11-16 disclose the similar arrangement where the blade 321 of the proximal side of the cutter 32 does not extend[] generally perpendicular” to the distal leading side (coincident with needle 31). Accordingly, the claimed features are not taught in Irisawa.

Further, Irisawa does not operate similarly to the features of the present claims. In Irisawa, the needle is first used to puncture the surface of the blood vessel. The needle is then extended through the lumen to puncture another point in the blood vessel. The surgeon pulls on the needle to isolate a section, and then slides the blade 32 along the blood vessel to cut an opening in the vessel. The features of the present claims would not work in such an environment. By way of contrast, the application discloses a cutting blade that punctures in a first direction relative to the shaft and then cuts in a second direction that is generally perpendicular to the first direction. The simplicity of the arrangement of the device of the present claims provides for a proper sized cut, even on a beating heart.

In this case, the blade and shaft are used to determine the proper size of the opening in the blood vessel. The device of Irisawa includes a mechanically operated stop 41 to prevent a cut that is too large. The device of the present claim is simpler, and requires fewer features for the surgeon to manipulate. Without the stop 41, the surgeon would not be prevented from making an overly large cut. Further, the device of Irisawa can still make a cut that is too large or too small. The needle extending through the lumen is designed to puncture an exit hole so that the opening will extend from the entrance puncture to the exit puncture. If the surgeon catches the needle on the inside of the lumen prior to the stop reaching the entrance puncture, the surgeon can be fooled into thinking the stop is against the entrance puncture. This mistake can occur quite frequently, and is made especially more likely when used on a beating heart. In this case, the opening would be too small.

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Given the problems of the Irisawa, one would not be likely to use the reference alone or in combination with another reference to show solve the problem involving cutting a precise opening in a blood vessel. Irisawa teaches adding other elements, such as the needle 31 and the stop 41 to the device of Shapiro to improve precisely cutting an opening but does not solve the problem. With the device of the present claims, the surgeon can always make a cut of the predetermined size and is much simpler than the device of the prior art.

Accordingly, because the features of claims 1 and 18 are not taught or suggested in the prior art, they would be missing from any proposed combination of the features.

Applicants request removal of the rejections of claims 1 and 18.

Claims 2-6, 15-17, 21-23, and 32-34 depend from patentably distinguishable claims 1 and 18, respectively. These claims further define the limitations of patentable claims 1 and 18. Further the additional reference Taylor in the rejection of claims 4-6, 15-17, 21-23, and 32-34 does not teach or make obvious the above-identified claimed features missing from Shapiro and Irisawa. Applicants also respectfully request removal of the rejection of the dependent claims.

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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-6, 15-23, and 32-34 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-6, 15-23, and 32-34 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

Cynthia T. Clague et al.,

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